

the pourable solid granules with a particle size of 20-1000 μm . Claims 16-19 of the '318 patent call for a process for producing such fibrin tissue adhesive formulation.

Claims 18-33 of the present application call for a biodegradable depot medicament formulation comprising: (i) a carrier system comprising a biodegradable blood plasma protein, which has been dried by fluidized bed drying with retention of its properties, wherein said blood plasma protein is selected from the group consisting of thrombin, fibrinogen, albumin, and mixtures thereof, and wherein the carrier system is in the form of microporous granules with a particle size in the range from 20 to 500 μm , and (ii) an active ingredient, which is to be administered as a depot or as an active ingredient combination. Claim 34 calls for a process for producing the depot medicament formulation of claim 18.

Accordingly, the scope of the claims of the present application differs from the scope of the claims of the '318 patent in at least two aspects:

(i) while claims of the present application are directed to a biodegradable depot medicament formulation comprising a carrier system and an active ingredient, the claims of the '318 patent are directed to a fibrin tissue adhesive (sealant);

(ii) while claims of the present application encompass formulations comprising both a biodegradable blood plasma protein(s) and an active ingredient, the claims of the '318 patent encompass formulations containing a specific mixture of blood plasma proteins (*i.e.*, thrombin, fibrinogen and factor XIII).

It follows, that, in contrast to the Examiner's assertion, claims 18-34 of the present application are not co-extensive in scope with claims 1-19 of the U.S. Patent No. 6,596,318. Reconsideration and withdrawal of the double patenting rejection is believed to be in order.

Applicants therefore respectfully submit that WO 97/44015 cited by the Examiner does not anticipate the present claims. Reconsideration and withdrawal of the anticipation rejection is believed to be in order.

CONCLUSION

Applicants request entry of the foregoing remarks in the file history of this application. In view of the above remarks, it is respectfully submitted that pending claims 18-34 are now in condition for allowance and such action is earnestly solicited. If the Examiner believes that a telephone conversation would help advance the prosecution in this case, the Examiner is respectfully requested to call the undersigned agent at (212) 527-7634. The Examiner is hereby authorized to charge any additional fees associated with this response to our Deposit Account No. 04-0100.

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Respectfully submitted,

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